DEPARTMENT OF STATE HEALTH SERVICES INFORMED CONSENT
Investigational Stem Cell Treatment

The Texas Department of State Health Services (DSHS) requires written consent before an eligible patient to receives a voluntary investigational stem cell treatment. DSHS oversees the informed consent requirements. This follows Texas Health and Safety Code, Chapter 1003, Section 1003.054.

Patients must acknowledge:

Investigational adult stem cell treatment, as defined by Texas Health and Safety Code, §1003.051, means:

(A) it is under investigation in a clinical trial,
(B) administered to human participants in that trial; and
(C) is not yet approved for general use by the United States Food and Drug Administration (FDA).

My physician described the risks and hazards of this investigational stem cell treatment. I voluntarily agree to receive this investigational stem cell treatment. A certified physician will administer this treatment. Through the Texas Health and Safety Code, Section 1003.055 the physician received certification. And an institutional review board oversees the physician.

Patient Name _____

Administering Physician Name _____

Investigational Stem Cell Treatment/Clinical Trial Information _____

_____

I have read, understand and acknowledge that (initial below):

_____ I discussed treatment options with my primary treating physician about my diagnosed chronic disease or terminal illness. My treating physician documented this in my medical record. The treating physician recommends or prescribed in writing I receive the investigational stem cell treatment referenced above.

_____ This stem cell treatment is under investigation in a clinical trial. The FDA has not approved this treatment for general use.

_____ My physician provided me with a separate document(s) (attached) that provides consent related specifically to the investigational stem cell treatment prescribed for me. The document describes the risks and hazards related to the administration of the investigational stem cell treatment planned for me.

_____ My physician gave me an opportunity to ask questions about:

- my condition,
- alternative forms of treatment,
- risks of nontreatment,

- steps that will occur during my care related to investigational stem cell treatment,
- risks and hazards involved in the care and procedures and
- I believe I have sufficient information to give informed consent.

_____ My physician fully explained this informed consent form and treatment related to the attachment(s). I filled in any blank spaces.

By signing this, I acknowledge I have read and understand this consent form. I voluntarily agree to receive the investigational stem cell treatment listed on this form.

_____
Patient (or Legally Authorized Representative) Signature

_____
Patient Name (Print)

_____
Address (Street or P.O. Box)

_____
Date

The following administering physician ensured this informed consent was signed in conjunction with the investigational stem cell treatment consent. And associated attachment(s) meets or exceeds the requirements found in 45 CFR §46.116, as applicable.

_____
Physician Signature

_____
Physician Name (Print)

_____
Address (Street or P.O. Box)

_____
Date

Please keep a copy of this signed informed consent and a copy of the investigational stem cell treatment consent and associated attachment(s) in the patient's medical record.